

REMARKS

The present application relates to inbred maize plant and seed PH581. Claims 1-10 are pending in the present application. No new matter has been added by way of amendment. Applicants respectfully request consideration of the claims in view of the following remarks.

Detailed Action

Applicants acknowledge that copies of the PTOL-1449 and 892 forms from the parent application Serial No. 09/758,802, now U.S. Patent No. 6,717,037 have been received. The Examiner has requested a supplemental Information Disclosure Statement (IDS) citing those references previously cited on the 892 forms in the parent application. Applicants have enclosed herewith the requested supplemental IDS form.

Double Patenting

The Examiner rejects claims 1-6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending U.S. Patent No. 6,717,037. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method of producing an F1 hybrid with PH581 as one of the parents as claimed by the patent, to obtain the resultant F1 hybrid as instantly claimed.

Applicants is herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c), which disclaims any term of a patent issuing from this application which would extend beyond the term of copending U.S. Patent No. 6,717,037. Therefore, Applicants submit that the claims are in proper form for allowance and respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written description regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH581 with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. Claims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent". The Examiner further states "the specification only provided guidance for the traits exhibited by the single inbred parent PH581, and for traits exhibited by crossing a single inbred parent PH581 with one other inbred parents (see Tables 3A-3C). No guidance is provided regarding the genetic composition of PH581 at any locus or on any chromosome. No guidance is provided regarding the genetic composition of any of a multitude of non-exemplified inbreds or hybrids at any single locus or on any chromosome. Furthermore, no guidance is provided for the obtention or characterization of a hybrid plant which somehow contains an intact cell from an inbred parent". (Office Action, p. 3).

Applicants respectfully traverse this rejection. Applicants submit that the genus of F1 hybrids encompassed by Applicants' claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH581, which provide an identifying structural feature possessed by all members of the claimed genus. (See U.S. Patent No. 6,717,037; Table A, column 12, line 4 through column 13, line 61).

Exhibit 1, submitted herewith, is a visual representation of the fact that most of the cells in a corn inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes the ten chromosomes are represented by three rectangles in the Exhibits).

When the inbred is used to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells will receive one of the inbred's sets of chromosomes.

As known to one of ordinary skill in the art and as shown in Exhibits 2 and 3, attached herewith, when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. Therefore, the genus of F1 hybrid seed and plants encompassed by Applicants' claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH581. Stated in patent terms, it can be said that an F1 hybrid made with PH581 *comprises* the unique chromosomes of inbred PH581. This unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art.

For example, SSR markers publicly known at the time of filing this application can be used for this purpose. Applicants further point out that the unique set of chromosomes of PH581 that will be retained in a hybrid made with PH581 are described in the SSR profile in the copending parent application, U.S. Patent No. 6,717,037 (Table A, column 12, line 4 through column 13, line 61).

This set of chromosomes described and disclosed in the parent application, U.S. Patent No. 6,717,037; Table A, is present within the seed of inbred line PH581 deposited by Applicants at the ATCC. Further, this unique set of chromosomes can be characterized by molecular marker methods and specifically the SSR profile. (*See* U.S. Patent No. 6,717,037; Table A, column 12, line 4 through column 13, line 61). Therefore, while the Examiner has stated Applicants have not provided guidance, Applicants have provided guidance as to identifying characteristics of the entire genus of hybrids claimed.

According to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." The unique set of chromosomes of inbred maize line PH581 is an identifying structural characteristic present in Applicants' seed deposit of PH581. The SSR profile of PH581 is obtainable from the deposit by one of ordinary skill in the art, as evidenced by Table A of the published parent application, U.S. Patent No. 6,717,037.

The Examiner states "[c]laims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent". (Office Action, p. 3). One of ordinary skill in the art would know that the pericarp tissue is genetically identical to the maternal parent. It is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. The pericarp tissue that surrounds the seed is 2n maternal tissue only, the embryo is 2n tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is 3n tissue resulting from the fusion of two maternal and one paternal gametes. The seed of maize has been described as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel. Therefore, Applicants point out that intact cells from inbred PH581 will be a component of the

F1 hybrid seed produced with PH581 as the maternal parent. Further, the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH581 and can be characterized by molecular markers. (For example, see U.S. Patent 6,717,037; Table A, column 12, line 4 through column 13, line 61).

As stated above, the essential test of written description is whether Applicants have demonstrated possession of a claimed invention such that one skilled in the relevant art would recognize that the Applicants were the inventors of the invention as claimed. Applicants have taught that the main utility of an inbred line is to produce F1 hybrid seed and plants. (*See* Specification, p.15, lines 2-3). As the Examiner has acknowledged, Applicants have provided guidance for the traits exhibited by crossing the inbred parent PH581 with another inbred parent thereby producing an actual F1 hybrid seed and plant. Applicants have made a deposit of inbred PH581 that fully enables others to make the genus of F1 hybrid seed and plants of claims 1-10. Further, Applicants previously disclosed the SSR profile of PH581 that further describes a specific identifying characteristic other members of the genus of F1 hybrid seed and plants of claims 1-10. One skilled in the art would thus recognize that Applicants were in possession of F1 hybrid seed and plants produced from line PH581 as of the filing date of the application.

B. Enablement regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH581 with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. (Office Action, p. 5).

The Examiner states that Kevern, U.S. Patent No. 5,850,009 suggests "[t]he use of *breeding crosses* to obtain particular desirable corn individual possessing a particular genetic and morphological complement of traits is unpredictable, due to the large number of genes involved,

and the interaction of these genes with selection methods, environmental effects, breeder actions." (*See* Kevern, column 4, lines 37-46, emphasis added). (Office Action, p. 6).

Applicants respectfully traverse. The Examiner refers to a section of Kevern (column 4, lines 37-46) that is specifically discussing segregating populations of seed. A segregating population is not the invention claimed in claims 1-10. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Rather, the F1 hybrids of the present application are based on stable inbred lines where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH581, as may be further exemplified by the SSR profile. Kevern states:

"Maize is an important and valuable field crop. Thus a continuing goal of plant breeders is to develop high-yielding maize hybrids that are agronomically sound based on stable inbred lines. The reasons for this goal are obvious: to maximize the amount of grain produced with the inputs used and minimize susceptibility of the crop to pests and environmental stresses. To accomplish this goal, the maize breeder must select and develop superior inbred parental lines for producing hybrids" (column 4, lines 23-31).

Applicants assert that in order to accomplish the goal of developing maize hybrids it is necessary to identify genetically unique and stable inbred lines, such as the claimed invention, in order to produce the F1 hybrid seed. It is vital to conceptually understand that the cited section of Kevern by the Examiner is not describing the use of stable inbred lines to produce F1 hybrid seed. An F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics may be exemplified by the SSR profile present in both the inbred and the F1 hybrid (*see* U.S. Patent No. 6,717,037; Table A, column 12, line 4 through column 13, line 61). In contrast, Kevern is describing the development of a genetically segregating population which is distinct from genetically stable F1 hybrid seed. Therefore, Applicants respectfully state the Examiner has misinterpreted the claimed invention and inappropriately applied Kevern to the present invention. The use of stable inbred lines, such as PH581, does allow for one of ordinary skill in the art to make F1 hybrids produced from inbred line PH581.

The Examiner also cites Carlone, U.S. Patent No. 5,763,755 stating that "the usefulness of a multitude of hybrids produced by crossing a single inbred with a multitude of non-exemplified breeding partners is unpredictable, given the polygenic nature of inheritance of many agronomic traits, the difficult of predicting the expression of said traits in hybrid progeny of inbreds which do not express them, and the failure of those collections of traits to be

transmitted to progeny of parents containing them (see e.g., Carlone, columns 1-2)". (Office Action, p. 6).

Applicants traverse this argument. The Examiner cites Carlone which states:

"Maize breeders select for a variety of traits in inbreds that impact hybrid performance along with selecting for acceptable parental traits. Such traits included yield potential in hybrid combination; dry down; grain moisture at harvest; greensnap; resistance to root lodging; resistance to stalk lodging; grain quality; disease and insect resistance; ear and plant height; performance in different soil types such as: low level of organic matter, clay, sand, black, high pH, low pH; performance in: wet environments, drought environments, and no tillage conditions. These traits appear to be governed by a complex genetic system that makes selection and breeding of an inbred line extremely difficult. Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it [the inbred] may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlone, paragraph bridging columns 1 and 2, language in [] added by Applicants for clarification).

Carlone is discussing the traits of the inbred (or parental) line and their development. The referenced section of Carlone is specifically discussing selection within the segregating populations of seed that a breeder uses for inbred development. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Further, the patent cited by the Examiner is one in which Carlone developed a novel inbred line and sought and was allowed claims to the hybrid seed and plants produced from the novel inbred line. Therefore, Applicants respectfully state the Examiner has misinterpreted the cited portion of the Carlone reference and has inappropriately applied Carlone to the present invention. The use of stable inbred lines, such as PH581, does enable one of ordinary skill in the art to create hybrids comprising the disclosed chromosomes of PH581.

The Examiner goes on to cite Stuber *et al.* stating that the cited reference teaches that "grain yield and ear number were strongly affected by environmental influences such as plant density, and that epistatic genetic interactions prevented accurate performance prediction of particular hybrids derived from particular crosses (see, e.g., page 503, Abstract; page 505, column 1, first and third full paragraphs; page 506, paragraph bridging the columns)". (Office Action, p. 6).

Applicants traverse this argument. Applicants assert that Stuber *et al.* is comparing synthetic populations and not F1 hybrids as taught by the present application. (See Stuber *et al.*,

p. 503 under *Materials and Method*, where Stuber notes that all possible crosses, including 3-way and double crosses, were made). In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH581. (Specification, p. 15, lines 2-4). Thus, Applicants respectfully state the arguments set forth by the Examiner do not apply to the presently claimed invention.

The Examiner also references Melchinger *et al.* stating that the reference teaches "that epistatic effects reduced the amount of heterosis in hybrid crosses" (see, e.g., page 231 column 1, bottom paragraph; column 2, first paragraph of Introduction; page 223, column 2, bottom paragraph; page 237, column 1, top paragraph). (Office Action, p. 6).

Applicants traverse this argument. As discussed *supra* with respect to Stuber *et al.*, Applicants assert that Melchinger *et al.* is discussing the making of all possible crosses including F2, 3-way and backcrosses, to produce a population of seed (Melchinger, first sentence of Summary). In contrast, the claimed invention teaches the use of a stable and reproducible inbred line to produce a stable and reproducible F1 hybrid. Thus, Applicants respectfully assert the arguments set forth by the Examiner do not apply to the presently claimed invention.

In addition, it is important to note that the claimed F1 hybrid seed is routinely and easily produced by crossing a plant from an inbred maize line PH581 with a plant from another inbred maize line. Applicants have made a deposit of inbred PH581 that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids.

The Examiner also goes on to state that "[t]he plant resulting from the diploid embryo may contain genetic material from both parents, but does not contain any intact egg or sperm cell (or any other type of cell) from the inbred parents". (Office Action, p. 7).

Applicants reiterate that a maize seed is comprised of various components, such as pericarp, embryo and endosperm. The origin of the gametes is not simply the result of fusion of a haploid sperm (pollen) and haploid egg (ovule) to form a diploid embryo. As explained previously, the pericarp tissue is genetically identical to the maternal parent. Thus, one would produce the claimed F1 hybrid by using inbred PH581 as a maternal parent.

Accordingly, Applicants submit that claims 1-10 are fully enabled. In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Summary

35 U.S.C. § 112, first paragraph - Written Description and Enablement regarding Claims 1-10

Applicants submit there has been adequate written description and a reduction to practice of the claimed F1 hybrid genus. The genus of F1 hybrids encompassed by Applicants' claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH581, which provide an identifying structural feature possessed by all members of the claimed genus. Specifically, the genus of F1 hybrid seed and plants encompassed by Applicants' claims all share the common structural attribute of having a complete set of the chromosomes of PH581, and a description of the set of chromosomes is disclosed in Table A of the published parent application, U.S. Patent No. 6,717,037. In addition, the SSR profile of PH581 is obtainable from the deposit of PH581 by one of ordinary skill in the art, utilizing SSR markers publicly known at the time of filing this application. In addition, the F1 hybrid seed also will comprise an intact cell from inbred maize line PH581 when PH581 is the maternal parent. Therefore, one of ordinary skill in the art would thus recognize that Applicants were in possession of F1 hybrid maize seed and plants produced from PH581. Applicants respectfully submit that claims 1-10 are adequately described.

Applicants also respectfully assert that the claimed invention is enabled by the present application. The claimed F1 hybrid seed is produced by crossing a plant from inbred maize line PH581 with a plant from another inbred maize line whereby the F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it. Seed of inbred line PH581 has been deposited and it is well known to one skilled in the art how to use PH581 to produce F1 hybrid seed. Applicants have created a novel maize inbred line PH581, and by virtue of the deposit of PH581, one of ordinary skill in the art is fully enabled to produce inbred maize line PH581 and F1 hybrid seed and plants produced from PH581.

It is respectfully submitted that Applicants have described and enabled the production of the F1 hybrid seed and plants produced with PH581, and are entitled to the scope of their invention as claimed.

Applicants further acknowledge that the claims (1-10) are deemed free of the prior art. The Examiner further states the prior art fails to teach or suggest inbred maize plant PH581, or methods of using it.

Conclusion

In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Please consider this a one month extension of time from March 17, 2005 to April 17, 2005, under the provision of 37 C.F.R. § 1.136(a) and charge Deposit Account No. 26-0084 for the amount of \$120.00. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any fees inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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